

SCIENCE & GOVERNMENT REPORT

24th Year of Publication

The Independent Bulletin of Science Policy

Volume XXIV, No. 12

P. O. Box 6226A, Washington, D. C. 20015

© July 1, 1994

R&D Budgets Taking Hits As Congress Votes Funds

For research budgets, the news is generally bad on Capitol Hill, where the first round of spending decisions has been coming out of the House Appropriations Committee in recent weeks.

Neither the National Science Foundation nor the National Institutes of Health got as much as they hoped for—and they weren't hoping for much above this year's budget. With increases of under 3 percent at this point, both are headed for a fiscal standstill, or worse, next year. To worsen matters, it is mainly their grantee institutions that will have to bear the "pause," or freeze, that the White House has ordered in indirect cost payments on research awards.

The basic-research budget of the Department of Energy is in a nosedive, following termination of the Superconducting Super Collider. Last year, with the SSC budgeted for \$640 million, DOE received a total of \$1.6 billion under the heading of General Science and Research Activities, which

NIH Head Agrees to French Request To Re-Examine AIDS Patents—P. 5

mainly means particle and nuclear physics. After Congress killed the SSC, the money remaining in the pipeline was designated for close-out costs. Hopes persisted that after the burial was completed, resources destined for the ill-fated SSC would be redeployed to other DOE basic science projects. But that hasn't happened.

From \$1.6 billion delivered for this year, the DOE science appropriation sought by the White House for next year dropped to \$1.1 billion, of which \$180 million was to be added to the close-out account. Noting the heaps of termination money on hand, the House Appropriations Committee refused to provide additional close-out funds. The outcome, endorsed by the full House, was \$989 million for DOE basic science next year, \$626 million below this year's appropriation. The money that would have been spent on the SSC if it had survived is nowhere to be found.

The budget news, however, is not entirely bleak. The House Appropriations Committee, and then the full House on June 27, did well by the new R&D favorite in the federal establishment, the National Institute of Standards and Technology (NIST), raising its budget from \$520 million this year to \$840 million next year.

The NIST increase is about \$100 million less than the White House request, which focused mainly on increasing NIST's industrial-assistance programs. The core of that

(Continued on Page 2)

Apologies and Alibis at Dingell's Cancer Hearing

Publicly battered for sloppy management of breast-cancer research, officials of the University of Pittsburgh and the National Cancer Institute groveled in Congress last month, expressing contrition for their failings and homage to Chairman John Dingell and his Oversight and Investigations Subcommittee for exposing them.

Parroting a favorite Dingellism, Pitt Chancellor J. Dennis O'Connor unctuously noted that the "Subcommittee has a reputation for sharp teeth." Nonetheless, he confessed to the prosecutorial Chairman, "We are learning that sharp teeth can be painful and embarrassing but, unfortunately, can also be necessary from time to time."

O'Connor pledged unrestrained efforts to clean up the

(Continued on Page 3)

In Brief

From a memo by a highly qualified PhD concerning a job interview recently at the White House Office of Science and Technology Policy: "The first person I was to see at OSTP never showed up, and the others seemed preoccupied with tasks they were unable to describe so that I could understand the mission of the place. During our 30-minute interview, their primary concern seemed to be whether I would be comfortable answering my own phone and making my own appointments. My attempts to move the conversation to issues of substance, like what the job entailed, what projects I might be involved in, etc., got nowhere." P.S. He got a good job elsewhere.

Multiple Portraiture: The June 17 issue of *Psychiatric News*, publication of the American Psychiatric Association, contains seven photos of newly installed APA President John S. McIntyre, MD. In separate pictures, five on the cover, there's McIntyre with his wife, with Tipper Gore, with his children, delivering his Presidential address, and just standing at a Presidential reception. Inside, there's McIntyre cutting an APA birthday cake and presenting a Special Presidential Commendation.

Having completed a study of its intramural research program at the request of its House Appropriations Subcommittee [SGR, May 15], NIH has just been directed by the Subcommittee to undertake a study of the extramural program, with a February reporting date.

Off the press next week: The Funding of Young Investigators in the Biological and Biomedical Sciences, a report for a symposium July 7 at the National Academy of Sciences. Copies, \$24.50, plus \$4 for shipping, from: National Academy Press, 2101 Constitution Ave. NW, Wash., DC 20418; tel. 1-800/624-6242; or 202/334-3313.

... \$900 Million Cut in DOD's University Research

(Continued from Page 1)

effort, the Advanced Technology Program, soars from \$195 million to \$431 million. Though NIST's percentage gains are impressive, it is still in the minor leagues of federal R&D spending. After it hits the billion-dollar mark, gains will come harder.

Rescue efforts on the floor and in the Senate may alleviate the disappointments of the less-favored agencies. But money is so tight in this year's deficit-cutting appropriations process that the legislators have little room for maneuvering.

Meanwhile, it's nip and tuck in a bizarre political episode involving a huge chunk of Defense research money that had all along been considered a sure thing.

In the biggest, and least expected budget blow, delivered June 27, the House Appropriations Committee cut \$900 million from the \$1.8 billion budgeted for next year for university-based research financed by the Defense Department. Since the Pentagon's current spending in this category is at approximately that same \$1.8 billion level, the Committee's action entailed a real loss, as distinguished from the reductions in hoped-for increases that disappointed federal beneficiaries slyly misrepresent as "cuts."

Following an outcry from academe's Washington outposts, the perpetrator of the \$900-million mayhem, Rep. John Murtha (D-Pa.), said he would reconsider his handiwork later in the appropriations process. However, once money is deleted, fiscal restoration is a daunting task in the present circumstances.

Murtha, who chairs the Defense Appropriations Subcommittee, is one of the barons of the House—and in this instance, he was an irritated, score-settling baron. Lavish with earmarked funds for colleges and universities in and around his own district, as well as for projects sought by colleagues for their hometown schools, Murtha had long eluded the anti-earmark crusade of Rep. George Brown (D-Calif.), Chairman of the House Science, Space, and Technology Committee.

Though Brown was initially regarded as a harmless crank who sought to deprive his fellow Congressmen of their historic right to bring home the bacon, he has been making progress against earmarks—spending directives slipped into money bills without the approval of the government agencies that must write the checks. Brown, in harmony with the big academic recipients of research funds, says earmarks misdirect scarce science money by substituting political pull for peer review. Last year, Brown claimed to have thwarted hundreds of millions of dollars in earmarks by pressuring universities to shun them and encouraging federal agencies to resist earmark directives.

Continuing his campaign, Brown became an even greater irritant last November when he requested the Pentagon's records of the earmarkings, many of which are hidden in obscure thickets of the military's immense budgets. In response, the Pentagon said that the staff of Appropriations

FASEB Altering Tax Status

Already more active in lobbying for research money than perhaps any other scientific society, the Federation of American Societies for Experimental Biology (FASEB) has applied for a less-restrictive federal tax-exempt status "to allow it to engage in a level of lobbying commensurate with the Federation's new, expanded mission in public affairs."

The quote is from the June *Newsletter* of FASEB, a consortium of nine professional societies with a collective membership of 41,000. With an association budget of \$16 million, according to FASEB Comptroller John Rice, the organization currently spends about \$700,000 a year on lobbying activities such as Congressional testimony and grassroots mailings.

The 501(c)(3) tax status, which FASEB plans to retain, prohibits "substantial" lobbying. The 501(h) that it is seeking sets out a formula that Rice says would allow as much as \$1 million a year for lobbying. The change, he said, would provide a firmer basis for lobbying and does reflect plans for a bigger effort.

Chairman Murtha had advised it to deny the request. Brown thundered back that he would have his Committee issue a subpoena to force release of the records.

The issue was finally settled in Brown's favor at a summit presided over by House Speaker Tom Foley. Last week, Brown's staff was still poring over the earmark records when Murtha struck—slicing out the \$900 million, much of which was slated for research universities in the forefront of the anti-earmark movement. The report from Murtha's Subcommittee blithely attributed the reduction to "fiscal constraints."

Murtha has since indicated that he will reconsider the matter later on in the appropriations process. It's thus possible that some if not all of the money will be restored. As for Brown's anti-earmark campaign, it may be that it has gone as far as it can go.

With money in tight supply, the case for judicious distribution is strengthened, but then so is the impulse to grab a share in the dead of night.

© 1994, Science & Government Report, Inc.

Editor and Publisher
Daniel S. Greenberg

Associate Publisher
Wanda J. Reif

Circulation Manager
Glen D. Grant

Published by Science & Government Report, Inc., twice monthly, except once each in January, July, August, and September. Annual subscriptions: Institutions, \$425.00 (two years, \$730.00). Bulk and individual rates upon request. Editorial offices at 3736 Kanawha St. NW, Washington, DC 20015. Tel. (202) 244-4135. For subscription service: PO Box 6226A, Washington, DC 20015. Tel. 1-800-522-1970; in Washington, DC 785-5054. Reproduction without permission is prohibited. SGR is available on University Microfilms International. Claims for missing back issues will be filled without charge if made within six weeks of publication date. ISSN 0048-9581.

... Pitt Attributes Failings to "Culture of Deference"

(Continued from Page 1)

mess that originated at his university, while assuring Dingell that "the knowledge that we are and will always be imperfect does not discourage us."

NCI Director Samuel Broder brought word of newly discovered record-keeping discrepancies in the long-running, widely dispersed cancer-treatment trials that Pitt has managed for decades for NCI.

He, too, put on a show of deference to the Dingell team. Though Dingell's committee staffers are privately regarded at NCI and the rest of the National Institutes of Health as nit-picking troublemakers looking to glorify their boss, Broder seconded O'Connor in hailing "the important contributions of committee staff." Another Pitt official, Thomas Detre, Vice Chancellor for Health Sciences, genuflected in his testimony to "the distinguished staff of Mr. Dingell's committee."

The hearing, held June 15, was Dingell's second public round on flawed record-keeping and other mishaps in the series of cancer trials known as the National Surgical Adjuvant Breast and Bowel Project (NSABP). Spread over 500 locations, with Pitt as the organizer and orchestrator, the project began in the early 1970s and has enrolled scores of thousands of patients in what are generally regarded as the most complex and fruitful clinical cancer trials ever staged.

Dingell's initial hearing, in April, was inspired by press reports of the enrollment of ineligible patients in trials conducted at St. Luc Hospital in Montreal [SGR, April 15: "NIH Takes a Beating at Dingell's Cancer Hearing"]. The reports were accompanied by allegations of delays and administrative confusion at Pitt and NCI in dealing with the enrollment problems.

With cancer patients and their support organizations expressing consternation at reports of disarray in the trials, Pitt and NCI officials insisted that the unwarranted enrollments were small in number and did not affect the research findings, which validated lumpectomy over mastectomy as the preferred treatment in many circumstances. Also at issue were delays in updating consent forms to acknowledge higher risks of uterine cancer from tamoxifen, a drug under trial in the NSABP.

But in combination with the dread of cancer, the word "fraud" was in the air—even uttered at Dingell's April hearing by NIH Director Harold Varmus. Dingell, who has long depicted the research establishment as unwilling to police itself, grasped the issue, setting off a flood of acute embarrassment for NCI and Pitt. For both institutions, the negative revelations about the trials have been a public-relations calamity, eroding the image of medical science as precise, caring, and responsible.

While staging a bell ringer on the smarm scale at last month's hearing, Pitt and NCI were also in hot pursuit of scapegoats to deflect attention from themselves. NCI's Broder said that reports of discrepancies in the research

managed by Pitt "languished in obscurity" at Pittsburgh, adding that "This is incomprehensible to us."

Officials of Zeneca Pharmaceuticals, manufacturer of tamoxifen, complained that managers of the research program failed to give them prompt notification of reported deaths among several patients enrolled in trials of the anti-cancer drug. "They should be providing that information to us as soon as it is known to them," Paul Plourde, Zeneca's Senior Director for Clinical and Medical Affairs, told the hearing.

Witnesses from NCI, Pitt, and Zeneca were in harmony in castigating 75-year-old Bernard Fisher, Pitt's manager of the research program, as the major culprit, though they first covered their flanks by fulsomely praising Fisher as an innovative pioneer in cancer research. This was a prudent tactic since Fisher, who was abruptly deposed as head of the project when the errors became public, had long been revered and honored as a miracle worker, and has served on Washington's topmost cancer advisory groups, including the President's Cancer Panel. NCI and Pitt said they failed by not reining him in.

Why? In providing an explanation at the June 15 hearing, Pitt picked up the theme previously voiced by NCI's Broder, who told Dingell's April hearing that NCI's staff wilted before "Fisher's formidable reputation." Broder said that mere government employees felt intimidated by the renowned Fisher and backed off when he failed to respond to their criticisms of his management of the research program.

Pitt Vice Chancellor Detre embellished the Broder explanation, ruling that his University has succumbed "to the culture of deference that has developed at universities over many, many years, if not centuries."

Thus alerted to a heretofore unreported failing in academia, the Subcommittee perked up. "Did that culture of deference at Pittsburgh toward Dr. Fisher, did that contribute to the University's failure of oversight?" asked Rep. Sherrod Brown (D-Ohio), who was right up there with Dingell in vigorously questioning the witnesses.

"I believe it contributes to any university's failure," Detre replied, "because we don't have a mechanism in place to truly supervise senior faculty."

Congressman Brown appeared concerned: "This culture of deference that you have labeled clearly can cause potential problems in university settings across the country," he said. "Do you see any role for the University of Pittsburgh to lead the way in beginning to undo some of that?"

Stating that it's a thankless task but someone has to do it, Detre declared: "We intend to be the leader in this, though I fully recognize, Congressman Brown, that it will not necessarily win a popularity contest."

While the Congressman continued to pick at the culture of deference, Detre managed to interject a point in behalf of the Pitt-managed NSABP, volunteering that "it was NSABP

(Continued on Page 5)

Pitt's Chancellor on the Congressional Griddle

The following exchange, between Rep. Sherrod Brown (D-Ohio) and Chancellor J. Dennis O'Connor of the University of Pittsburgh, took place June 15 at the House hearing on discrepancies in government-supported cancer-research trials administered by the University. The text, condensed by SGR, is essentially verbatim.

Brown. Dr. O'Connor, you stated, "I accept responsibility for past administrative shortcomings and deficiencies of the project." Tell the Subcommittee what you mean by accepting responsibility.

O'Connor. I accept the responsibility of putting together an administrative team, with Dr. [Thomas] Detre [Senior Vice Chancellor for Health Sciences] and Dr. [Ronald] Herberman [Interim Chairman of the cancer research project] which will review the grant and bring it up to an administrative quality that is demanded by the kind of work that it undertakes.

Brown. The situation is going to be costly. One is the cost to the government for investigating and auditing this whole situation; second is the cost to the University for conducting its various reviews and inquiries, and your coming here, and all that; and third is the cost of recruiting patients whose data was found, for a variety of reasons, to be unusable. Does Pittsburgh intend to reimburse the federal government for the cost incurred in this whole investigation of this matter?

O'Connor. It certainly is a point that is under discussion, and I think it will continue to be under discussion.

Brown. Under discussion among whom?

O'Connor. It certainly has been under discussion with NCI.

Brown. What are your thoughts on that today?

O'Connor. That I would like to keep the discussion going.

Brown. You would like to keep the discussion going. If you had to make the recommendation to your board of trustees today, would you recommend a specific amount that you reimburse the government, taxpayers,

anything, that you reimburse the full amount?

O'Connor. Congressman Brown, I don't have a specific figure in my head at this point. That is why I would like to keep the conversation going.

Brown. Do you think you owe us something back in dollar amounts—not specific dollar amounts, but do you think you owe a dollar amount to us?

O'Connor. Congressman, I need to examine that very carefully, very carefully.

Brown. You are in charge, right?

O'Connor. That is correct.

Brown. Can you assure the Subcommittee as a matter of policy that Pittsburgh will characterize and categorize all the costs associated with this situation as unallowable for federal reimbursement? In other words, the law firms and whomever you may have retained or hired or expended monies upon, that you will not ask any of that for federal reimbursement?

O'Connor. That is correct, sir.

Brown. Okay. Does the University of Pittsburgh plan to reimburse the federal government for costs associated with generating significant amounts of unusable data? Should taxpayers pay for that?

O'Connor. We have not yet come to a conclusion on that yet.

Brown. What is your thinking as the person in charge?

O'Connor. Sir, I think there are multiple costs involved, and if there are legitimate costs that we should reimburse, then the University's position is that it will reimburse.

Brown. Give me some examples of what you would consider legitimate costs that you should reimburse for.

O'Connor. I don't have one off the top of my head.

Brown. Since you can't come up with any costs that you should reimburse us for, are there any you shouldn't reimburse us for?

O'Connor. There may be costs that the federal government should be reimbursed for and, as I said, the University will do that. But I don't have a compilation of those costs in front of me right now.

Mikulski Readies New NSF Charter

Senator Barbara Mikulski (D-Md.), who terrorized the NSF community last year with demands for more emphasis on "strategic research," relented on that theme for a while, but now she's back with a legislative draft that would enshrine eight trendy research topics in the Foundation's basic statute—biotechnology, advanced manufacturing, global change, and so forth. Having worked up the draft mainly on her own, the Senator has inspired concern, if not panic, at the Foundation and among its clients.

The Mikulski plan, which would run for five years, is taken very seriously in NSF ranks, since the Senator presides

over NSF's budget as Chairman of an Appropriations Subcommittee and also sits on the Labor and Human Resources Committee, which writes NSF legislation.

For NSF, the good news about her bill is that it would authorize annual increases that would raise NSF's budget from the present \$3.1 billion to \$5 billion in 1999, with a lot of the additional money slated for long-neglected lab construction and instruments. The concern arises from the lack of consultation with the NSF leadership and the imposition of industrial-related goals that clash with NSF's traditional emphasis on investigator-initiated basic research. But with the clock running out, the bill may languish.

Varmus in Quick Reversal on Gallo Patent Dispute

In a sudden, unexpected turnabout, NIH Director Harold Varmus has agreed to reopen the long-untouchable issue of Robert Gallo's disputed role in the identification of the AIDS virus and the allocation of lucrative patent royalties between the US and the Pasteur Institute.

In the Gallo affair, the patent controversy is the last surviving issue of a legal nature since Gallo walked free of scientific misconduct charges in 1992. Though the Office of Research Integrity (ORI) in the Department of Health and Human Services stood by its findings of misconduct, it declined to contest Gallo's appeal on the grounds that it couldn't meet newly prescribed evidentiary standards. Federal prosecutors also stood aside, citing the statute of limitations and other technical factors.

Varmus's move roughly coincided with the restricted distribution of an Inspector General (IG) "investigative memorandum," dated June 10, that cites doubts about Gallo's claims to priority. The report, from the IG's office in the Department of Health and Human Services, drew an angry response from Gallo's attorney, Joseph Onek, who said it's filled with errors. He particularly referred to the IG's damning assertions about Gallo's reliance on research pioneered at Pasteur.

Meanwhile there are reports that Gallo, who has spent his

career at the National Cancer Institute, has recently had serious talks about joining the Medical University of South Carolina. Attorney Onek told SGR last week that Gallo has been discussing a post in South Carolina, "among others." Gallo says he's under a "gag order" from NCI Director Samuel Broder and cannot speak for publication.

Varmus and other members of the NIH senior staff met privately June 28 with the head of the Department of Health and Human Services Office of Research Integrity and other HHS officials, with the Gallo case reportedly the sole item on the agenda.

The reversal of attitude by the NIH Director, initially reported by the preeminent bird dog of the Gallo affair, John Crewdson, in the *Chicago Tribune*, is reflected in a recent exchange of letters between Varmus and Maxine Schwartz, Director General of the Pasteur Institute.

In a letter dated June 8, Varmus rejected Pasteur's request for a reallocation of the patent royalties, which have amounted to \$20.1 million for the US and \$13.9 million for Pasteur since 1987. Gallo and several colleagues have annually received \$100,000 each in royalty payments. The NIH Director declared the case closed, suggesting that all involved should "put the matter behind us."

(Continued on Page 6)

Breast Cancer

(Continued from Page 3)

that discovered the cheating at Montreal, not another agency."

Fisher, cut adrift by his once-admiring colleagues, testified in his own behalf, complaining that NCI denied him needed funds for auditing the widely dispersed, complex program of surgical and pharmacological breast-cancer treatment trials. His request for \$180,000 for audits resulted in only \$80,000 for that purpose. Asked whether he requested additional money for audits, Fisher replied, "Yes, we did, in the years 1989, 1990, 1991, and so on." But the outcome was "either level or reduced funding each year," he said, though the number of patients in the studies rose from 25,000 in 1991 to 41,000 in 1993. Fisher said his records at Pitt corroborate his account of appealing for audit funds to match the increased patient load.

But NCI's Broder scoffed at Fisher's allegations. "I do not believe they are understaffed," he said of the audit operations at Pitt, "and I am not sympathetic, at least excessively sympathetic, to the argument that most of the problems that we have had today are focused on resources." Broder attributed the difficulties to a deeper problem: "We have to, without fear or favor, as much as human beings can, accept data as they come in." He added, "It is very dangerous for a scientist or a doctor to ignore facts..."

Fisher repeatedly said that the findings of the trials were not affected by the inclusion of a relatively small number of patients who did not meet the criteria for enrollment. Addressing charges that data on these patients were included in

published reports after they had been identified as ineligible, Fisher countered that their inclusion was recommended by the project's biostatisticians. Though ineligible by the enrollment criteria, he said, they still yielded useful data.

Regarding tardy changes in patient consent forms after several deaths were reported among patients taking the anti-cancer drug tamoxifen, Fisher claimed that the causes of death were initially unclear. In any case, he said, the findings in favor of lumpectomy over mastectomy and the protective powers of tamoxifen remain unchallenged. But Fisher at times appeared weary and confused and unaware of record-keeping discrepancies reported by Dingell's indefatigable investigative staff.

When Dingell asserted that "one site had three quarters of the participants ineligible," a flustered Fisher responded: "I am certainly unaware of that, sir. I am really not aware of it." With Dingell concentrating on the eligibility issue, Fisher tried to explain that "eligibility is not falsification." The Chairman, however, brushed that aside, complaining about Fisher's "lack of familiarity" with adverse findings.

Dingell pounded hard at Fisher, noting that the Pittsburgh project solicited funds from Zeneca for entertainment at annual gatherings of the NSABP investigators and staff, and that party funds and audit funds were about \$80,000 each per year. The Chairman depicted Fisher as "more expansive with your expenditures for parties than you are with your auditing."

"I don't believe it to be so," Fisher replied, noting that "after a lifetime of dedication to science," he felt Dingell's depiction of him was "absolutely devastating."—DSG

... IG Report Faults Gallo on Patent Application Data

(Continued from Page 5)

"The key facts," Varmus wrote, "are that a French virus was used by the American scientists who developed the test kit, and that American scientists developed and patented that test kit invention. Each contribution was necessary to the final result. I share your sense that the acknowledgement of the role of the *Institut Pasteur* in isolating the AIDS-causing virus was slow to occur.... I also recognize," Varmus continued, "the contribution of the scientists at the National Institutes of Health, without which the test kit would not have been developed when and how it was. Both hands, as it were, were necessary to grip the problem."

Pasteur Director Schwartz responded on June 8, describing herself as "deeply shocked and greatly troubled" by Varmus's claim, as she put it, "that both French and American contributions proved necessary to develop the test kit."

In fact, she stated, "the French test kit was developed in the absence of any input from the American scientists whereas there is no evidence that the American test could have been developed if the American scientists had not received the French virus."

Citing political pressures in 1987 to share the scientific glory and the patent royalties, Schwartz wrote: "We settled in 1987 for one simple reason: senior officials of the Reagan Administration repeatedly told us that there were two viruses; they also told us that there was not a single document in their files which could remotely be construed as supporting the position that they [Gallo's group] used our virus...."

"Documents later released, as well as Dr. Gallo's own subsequent statements," Schwartz continued, "indicated that a coverup of the true facts was deliberately undertaken so that we would settle, and new experiments have shown that the virus 'isolated' by Dr. Gallo was in fact the virus sent by the *Institut Pasteur*. You cannot tell us that we must abide by a sharing of royalties based on what would appear as a previous Administration's deliberate fabrication, and go on an assumption that later proved incorrect."

Adopting a tone quite different from his June 8 letter, Varmus responded to Schwartz's strong words on June 22. "I genuinely regret the inference permitted by the part of my June 8 letter that spoke of the test kit as if there were only one, not two kits. When I wrote about our mutual contributions, I was referring to the kit developed at the National Institutes of Health, the kit I presumed to be the subject of your communications to me."

Commenting on what he described as Schwartz's allegations of "deliberate US Government behavior to your Institute's detriment," Varmus, stopping short of a denial, simply stated, "Neither the United States Attorney nor the Inspector General has established the deliberateness that you assume."

Then came a conciliatory note that was lacking in Varmus's June 8 letter: "Were I to be persuaded that a change in our current arrangement for distribution of royalties is warranted, I would surely take steps to see that a change is made."

"When we last spoke," Varmus's letter went on, "you reiterated your wish for an acknowledgement from me appropriate to the current state of knowledge: that the French virus was used by National Institutes of Health scientists in developing the American test kit."

"I am entirely open to taking steps that appropriately accomplish that goal, which you and I share."

Varmus suggested that lawyers for Pasteur prepare for US consideration "a concrete proposal setting forth the elements of such an acknowledgement." The lawyers for the two sides should talk it over, Varmus added, thus opening the way to a meeting that the Department of Health and Human Services has heretofore rejected.

The Inspector General's investigative memorandum, covering 35 pages, follows the early AIDS research and subsequent patent filings in fine detail. While not stating any conclusions, it is laden with items detrimental to the Gallo camp. Referring to Patent Office reviews of Gallo's applications, the IG memorandum states: "During 1986, the [patent] examiner rejected the pending claim in several Gallo et al. follow-on applications ... on grounds that the work of the IP [*Institut Pasteur*] scientists was 'prior art' to Gallo et al."

The memorandum asserts that though Gallo was intimately familiar with Pasteur's AIDS research, he did not fulfill the obligatory requirement of disclosure of "prior art" in making sworn statements on the patent application.

"The relevance of the IP work to that of Gallo et al. was affirmed by the PTO [Patent and Trademark Office] examiner, when she became aware of it," the IG states. "The examiner advised the OIG [Office of Inspector General] that, had she been aware of the IP prior art at the time she examined the blood test application of Gallo, she would have suspended prosecution of the Gallo application and declared an interference between the two applicants."

Pasteur later challenged the Gallo patent, the IG notes, but by then, "the Gallo patent had long since been issued."

The response by Gallo's attorney said the IG's memorandum "is filled with an extraordinary number of errors reflecting factual distortions, scientific illiteracy and obvious bias," but does not address the IG's statements concerning the patent examiner.

Depicting Gallo as scientifically surefooted in moving toward development of an AIDS blood-test kit, the attorney's response describes the French as selfishly mercenary in the face of a deadly health crisis.

"Needless to say," attorney Onck declares, "the [IG] memorandum never mentions the French blood test scandal. In 1985 French officials delayed approval of the Abbott blood test (derived from Dr. Gallo's work) so that the Pasteur test could be readied for market. As a result of this outrageous action, hundreds and perhaps thousands of French citizens were unnecessarily infected with AIDS. The OIG ignores this scandal because it demonstrates how far behind the French were in development of a blood test."

In Print

(Continued from Page 8)

Space Technology Innovation (six times a year; 20 pp., no charge), from the NASA office that tries to push space technologies into the general economy, reports on collaborations with industry, inventions and gadgets available for adoption, meetings, publications, etc.

Order from: NASA Office of Advanced Concepts and Technology, Code C, 300 E St. SW, Washington, DC 20546; tel. 202/358-0695; fax 202/358-3938.

Report of the Panel on NIH Research on Antisocial, Aggressive, and Violence-Related Behaviors and Their Consequences (150 pp., no charge; supply limited), tiptoes around the racially volatile issue of violence research, noting that NIH finances relatively little of it (\$54 million worth in fiscal 1992), and recommending a major expansion, with recognition of the "sensitive social and political implications." In plain language, that means avoidance of stereotyping, particularly genetic branding. On other grounds, however, NIH Director Harold Varmus gave the report a chilly reception upon its release June 2 at a meeting of the Advisory Committee to the Director of NIH. In the Washington listening posts of the social and behavioral sciences, the NIH chief is increasingly regarded as a hard-science royalist, an impression he reinforced at the meeting by contending that the social and behavioral sciences don't show the rigor and promise evident 25 years ago in molecular biology, and he wondered skeptically about the fruits of past research and the prospects for research that could actually reduce violence. However, the scientific doubts about violence research are overshadowed by mounting political enthusiasm, as reflected in last year's Congressional directive for NSF to consider setting up a Center for the Study of Violence. The NIH panel was co-chaired by Thomas H. Murray, Director of the Center for Biomedical Ethics, Case Western Reserve School of Medicine; Fred Plum, Chairman of Neurology and Neuroscience, Cornell University Medical College, and Daryl Chamblee, NIH Acting Deputy Director for Science Policy and Technology Transfer.

Order from: National Institutes of Health, Division of Science Policy, Analysis, and Development, Building 1, Room 218, Bethesda, Md. 20892; tel. 301/496-1454; fax 301/402-0280.

Semiannual Report to the Congress: No. 10, from the Office of the Inspector General (IG), National Science Foundation, covering October 1, 1993, to March 31, 1994, reports on assorted malefactions among NSF awardees, none of awesome dimensions in dollars or ethics. In the scientific misconduct category, which NSF handles quietly and efficiently, in contrast to the NIH process, the report notes a fairly constant load of about 80 cases, with 27 received and 34 "closed out" in the last half of fiscal 1994. Included are meditations on misconduct issues arising from collaborative research relationships. "There is much potential gain for junior scientists in collaborative relationships," the report

states, "but also a danger that senior collaborators will unfairly deprive junior colleagues of the credit due them." It adds, however, that "there is disagreement about the norms governing collaborative relationships ..."

Order from: National Science Foundation, Office of the Inspector General, 4201 Wilson Boulevard, Arlington, Va. 22230; tel. 703/306-2100; fax 703/306-0649.

The Dana Alliance for Brain Initiatives: 1994 Resource Directory (92 pp., no charge), another manifestation of *realpolitik* in biomedical research, the directory, intended for news and TV people, lists some 130 researchers described as ready to educate the public and policymakers on "the promising goals of neuroscience research." Listings are by name, malady, institution, and state. The Alliance was established in 1992, with Nobelist James D. Watson as orchestrator and the Charles A. Dana Foundation providing support.

Order from: The Dana Alliance for Brain Initiatives, 1001 G St. NW, Suite 1025, Washington, DC 20001; tel. 202/737-9200; fax 202/737-9204.

High-Stakes Aviation: US-Japan Technology Linkages in Transport Aircraft (144 pp., \$27 plus \$4 for shipping), from the National Academy of Sciences Committee on Japan, warns that Japan is shrewdly exploiting technological ties with the American aerospace industry to develop competitive strength in commercial aircraft markets. In response, the report recommends, the US should avoid protectionist or defensive measures and seek a "more balanced flow" of technologies between the two countries. The report was produced by a group chaired by Daniel J. Fink, a former aerospace executive, now in private consulting practice.

Order from: National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20418; tel. 1-800/624-6242, or 202/334-3313.

To Order or Renew

Science & Government Report
Northwest Station, Box 6226A
Washington, D.C. 20015

☐ Renew my subscription ☐ Enter my subscription

Institutional subscribers: one year, \$425.00 ☐
two years, \$730.00 ☐

Non-USA airmail, \$35.00 per year; non-USA surface
mail, \$15.00 per year additional

☐ Check enclosed ☐ Please Bill
Please charge to: ☐ MasterCard ☐ VISA

Account# _____ Exp. date _____

Signature _____

Name _____

Address _____

Zip _____

Toll-Free Subscription Service: 1-800-522-1970
In Wash., D.C.: 785-5054 / FAX: (202) 362-2790

In Print

Official reports and other publications of special interest to the research community

(Copies of publications listed here are available from the indicated sources—not from SGR)

Health United States: 1993 (GPO Stock No. 017-022-01252-9; 301 pp., \$19; add 25 percent for foreign orders), latest edition of the Public Health Service's annual assemblage of vital statistics and other health-related data, including spending on treatment, research, and training, nursing home occupancy, occupational injuries, contraceptive usage, etc., encompassed in 156 tables with accompanying commentary. An 11-page distillation of the basic numbers is enclosed with the volume. For information about obtaining the tables on diskettes: 301/436-8500.

To order the printed version: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, Pa. 15250-7954; tel. 202/783-3238; fax 202/512-2250.

Cleaning Up the Department of Energy's Nuclear Weapons Complex (78 pp., no charge), from the Congressional Budget Office (CBO), the money monitor of Capitol Hill, says the cleanup costs are huge but unknowable at this point for the decades-long accumulations of radioactive and other hazardous waste around DOE's 15 weapons facilities spread over 12 states. In 1988, the CBO recalls, DOE's estimates for the task ranged between \$66 billion and \$110 billion. Last year, with characteristic DOE largess, the spread expanded to \$400 billion to \$1 trillion. CBO says the Energy Department should clarify its cleanup priorities, with emphasis on public participation in decisionmaking, and invest more in developing cheaper remediation techniques. Starting with appropriations of \$1.6 billion in 1989, DOE's cleanup program is budgeted this year for more than \$6 billion—about twice the budget of the National Science Foundation. "Selectively reconsidering cleanup standards," CBO states, "and accepting some level of risk greater than zero, could substantially lower costs. That could free public funds for other programs, such as environmental cleanup efforts deemed to be of higher priority than some of DOE's cleanup problems." The report was written by Elizabeth Pinkston and Frances M. Lussier of the CBO staff.

Order from: Congressional Budget Office, Publications, 2d and D Sts. SW, Washington, DC 20515; tel. 202/226-2809; fax 202/226-2714.

Asian Aeronautics: Technology Acquisition Drives Industry Development (GAO/NSIAD-94-140; 18 pp., no charge), another on the trendy topic of commercial aviation manufacturing, of growing interest because it's a major but declining US export earner. This one, from the General Accounting Office (GAO), investigative agency for the Congress, says development of domestic aircraft manufacturing holds high priority in Japan, China, Indonesia, and Taiwan, all reported to be using strategies involving substantial

SGR Summer Schedule

The next issue of *Science & Government Report* will be published August 1, 1994.

government assistance, imported technologies, "strong emphasis on applied—as opposed to theoretic or basic—research," and "direct, synergistic links between military and civilian aeronautics projects."

The report states that the four Asian nations acquire technology directly or through manufacturing subcontracts from the US and Europe, often as a condition for purchasing western equipment. "Once acquired," the GAO observes, "these technologies can be honed and improved upon. Consequently, what starts as a subcontract to produce latches on cargo doors, for example, develops over time into fuselage, wing, and avionics manufacturing." Though not yet able to challenge American firms, the Asian aircraft industry is on the way, the GAO says, adding that "industry observers suggested to us that American companies could not afford the large capital expenditures incurred by Asian companies for aeronautics work."

The report was requested by the Subcommittee on Technology, Environment, and Aviation of the House Committee on Science, Space, and Technology.

Also from the GAO: **Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry** (GAO/RCED-94-110; 73 pp., no charge), says techniques for inspection of these products remains locked in the poke, prod, and look methods adopted in 1907, following the public uproar created by Upton Sinclair's retch-inducing novel on meat-packing, *The Jungle*. Referring to numerous prior reports calling for science-based modernization of the process, the GAO notes that the Food Safety and Inspection Service of the Department of Agriculture has directed the industry to adopt techniques designed to prevent contamination, the Hazard Analysis and Critical Control Point System. However, the report faults the agency for not also requiring microbial monitoring. The report was requested by the Subcommittees on Livestock and Department Operations and Nutrition of the House Agriculture Committee.

Fossil Fuels: Lessons Learned in DOE's Clean Coal Technology Program (GAO/RCED-94-174; 25 pp., no charge), praises the program as a "unique" and successful partnership between government and industry in sharing the costs of big projects for demonstrating environmentally attractive technologies for using coal. Since startup in 1986, the program has organized 45 demonstration projects, financed by \$4.5 billion from industry and \$2.75 billion from DOE. The GAO says DOE's advanced funding of the projects has encouraged industry participation. "The industry participants told us," the report states, "that they would not want to commit significant funds in the early years of a project if they perceived that the government might stop sharing costs before the projects were completed."

Order from: USGAO, PO Box 6015, Gaithersburg, Md. 20884-6015; tel. 202/512-6000; fax 301/258-4066.

(Continued on Page 7)

